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TC 1700 PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q63803

Hisao HIRAMATSU , et al.

Appln. No.: 09/817,251

Group Art Unit: 1723

Confirmation No.: 8044

Examiner: Tony Glen Soohoo

Filed: March 27, 2001

For: METHOD FOR STIRRING LIQUID

SUBMISSION OF EXECUTED DECLARATION UNDER 37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith is an executed Declaration Under 37 C.F.R. §1.132 signed by
Hironobu Oota.

Respectfully submitted,

A handwritten signature in black ink that appears to read "Kenneth W. Fields".

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Date: December 24, 2003



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DECLARATION UNDER 37 C.F.R. §1.132

Commissioner for Patents
Alexandria, VA 22313-1450

Sir/Madam:

I, Hironobu Oota, do declare and state that:

I graduated from Doshisha University, Faculty of Engineering, Department of Applied Chemistry in March, 1993.

Since April, 1993, I have been employed by Kyoto Daiichi Kagaku Co., Ltd. (present name: ARKRAY, Inc.), and since that time, have engaged in development of small-sized biochemical analysis apparatus and reagents therefor, development of small-sized immunological analysis apparatus and reagents therefor, and study of mechanism systems and arithmetic processing systems such as stirring mechanism, type of optical measurement, arithmetic processing method and magnetic card specification.

I am familiar with the prosecution of the above-identified patent application including the Office Action dated June 24, 2003.

The following experiment was conducted by me or my direct supervision in order to demonstrate the superiority of the method of the present invention in comparison with U.S. Patent 5,555,767.

EXPERIMENTATION

Whole blood (100 µL) was poured into a container according to Fig. 1 in the present application, followed by sealing, and was allowed to stand for 1 hour or more to completely precipitate the blood. The completely precipitated whole blood was stirred by using a nozzle according to the following conditions A to F. The top of the nozzle was inserted into the blood until the center of the depth and the following stirred amount

was sucked and then discharged. The stirring was carried out 9 times. Also, as a reference, whole blood completely stirred by a touch mixer was used as a reference.

TABLE 1

Condition	Sample amount	Stirred amount	Discharged positions		Remarks
A	100 μ L	70 μ L	in the air	left and right sides	Invention
B	100 μ L	70 μ L	in the air	center	Comparison
C	100 μ L	70 μ L	in the liquid	center	Comparison
D	100 μ L	30 μ L	in the air	left and right sides	Invention
E	100 μ L	30 μ L	in the air	center	Comparison
F	100 μ L	30 μ L	in the liquid	center	Comparison

After the stirring, 10 μ L of the whole blood at the center of the depth in the container was collected and mixed with 1 mL of hemolysate in a disposal microtube by using a touch mixer.

Absorbance of the hemolysate was measured with a measuring apparatus SP-IM (568 nm) manufactured by ARKRAY, Inc. The results are shown in Table 2 below.

TABLE 2

	Reference	Condition					
		A	B	C	D	E	F
1	0.6497	0.6243	0.6325	0.6236	0.6593	0.5255	0.5999
2	0.6489	0.6255	0.5946	0.4781	0.6652	0.5960	0.1649
3	0.6567	0.6308	0.6241	0.5820	0.6632	0.6219	0.6446
4	0.6466	0.6405	0.6169	0.6364	0.6730	0.6648	0.5450
5	0.6511	0.6406	0.6087	0.5924	0.6579	0.6841	0.5176
Mean	0.6506	0.6323	0.6154	0.5825	0.6637	0.6185	0.4944
SD	0.0038	0.0079	0.0145	0.0624	0.0060	0.0625	0.1906
CV	0.58	1.24	2.36	10.72	0.90	10.10	38.56

U.S. APPLICATION NO. 09/817,251
DECLARATION UNDER 37 C.F.R. §1.132

PATENT APPLICATION

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: December 17, 2003 Name: Hironobu Oota
Hironobu Oota